Exhibit 300: Capital Asset Summary

Part I: Summary Information And Justification (All Capital Assets)

Section A: Overview & Summary Information

Date Investment First Submitted: 2009-06-30
Date of Last Change to Activities: 2012-02-23
Investment Auto Submission Date: 2012-02-23
Date of Last Investment Detail Update: 2012-02-23
Date of Last Exhibit 300A Update: 2012-02-23
Date of Last Revision: 2012-02-27

Agency: 009 - Department of Health and Human Services **Bureau:** 10 - Food and Drug Administration

Investment Part Code: 01

Investment Category: 00 - Agency Investments

1. Name of this Investment: FDA ORA Mission Accomplishments and Regulatory Compliance Services

2. Unique Investment Identifier (UII): 009-000005317

Section B: Investment Detail

1. **Provide a brief summary of the investment, including a brief description of the related benefit to the mission delivery and management support areas, and the primary beneficiary(ies) of the investment. Include an explanation of any dependencies between this investment and other investments.**

The MARCS program is the primary IT mechanism for realizing ORA program goals that supports all FDA Field activities (except laboratories) including domestics, imports, and enforcement. MARCS directly supports the surveillance and promotes the safety of all FDA regulated products except tobacco. It also directly supports the programs of the FDA Offices OF, OMPT, and OGROP, and FDA Centers CBER, CDER, CDRH, CFSAN, and CVM. MARCS is a Business Process Improvement (BPI) effort built from the ground up with integration in mind and forms an Enterprise Resource Planning system that spans all of the electronic work flows of ORA except for processes specific to ORA laboratories. It aligns directly with Strategic Goal 2, Objective C of the HHS strategic plan: Advance Scientific Knowledge and Innovation; Invest in the regulatory sciences to improve food and medical product safety and enables FDA Centers to meet FDA Strategic Goal 4: Improve the Quality and Safety of Manufactured Products and the Supply Chain. FDA uses MARCS to: plan FDA field activities and assign staff to inspections, investigations, recalls, and other compliance activities; track and control samples and the results of laboratory analysis; collect and maintain information from field activities; collect performance data, particularly that related to FDAAA; send Prior Notice for food imports to Customs and accept import product information from Customs for screening; screen some 20 million import lines a year based on calculated risk (PREDICT); collect information about the facilities FDA regulates and those in

the import supply chain for risk-based targeting; provide FDA Centers with information on inspections, compliance actions, recalls, laboratory analysis and facilities. Primary beneficiaries of MARCS are the FDA personnel conducting surveillance and regulatory activities. This extends to the public as MARCS enables these surveillance and regulatory activities. MARCS is closely coupled with two other major ORA investments, ALM and RBIS. ALM provides functionality for ORA laboratories and quality. RBIS provides reporting and information on some 5 million foreign and domestic firms. Together, these three investments provide for all of the regulatory workflows of ORA. MARCS also interacts with FURLS, eLIST, and a number of smaller systems at FDA.

2. **How does this investment close in part or in whole any identified performance gap in support of the mission delivery and management support areas? Include an assessment of the program impact if this investment isn't fully funded.**

Because much of the data and work conducted by the FDA Centers converge within ORA, ORA faces a particular set of performance gaps – e.g., the ability to integrate data in various formats with divergent data definitions; work flows that begin in a number of different states and progress through various organizations; functionalities that are divided into different systems; and the fragility of point-to-point integration schemes that have been built up over time. MARCS is a complete departure from the past which was characterized by organic growth in response to particular needs without an ability to consider the holistic Agency needs. MARCS is being built from the ground with SOA using an ESB coupled with a BPMS and technologies to support offline and Remote Access Device (RAD) usage. SOA allows MARCS to build and reuse functionality that in the past has been duplicated multiple times with different implementations. Now, functionalities can be shared both across MARCS and with other related programs including ALM and RBIS. The ESB solves the problem of fragile point-to-point integration resulting in more robust and higher performance systems. The BPMS standardizes the approach to defining, describing, mapping, and implementing work flows. This also brings the building and modifying of work flows closer to Federal business personnel as the graphical and English language tools do not require a technical background. This produces a much more accurate and useful work flow in the final product and shortens times to modify work flows. MARCS is producing shared services in accordance with point 6 of the 25 point IT reform plan. Much of the work performed by ORA personnel is done in remote areas without network connectivity. This has never been comprehensively addressed by ORA. MARCS is designed to inherently support off-line/on-line operations through RADs - handheld devices that will improve the efficiency of field staff in completing work not done in an FDA office and when connectivity may be intermittent. MARCS is doing a holistic RADs implementation based on field integration and infrastructure requirements. If MARCS is not fully funded, then the movement towards this future structure will be delayed and work will need to continue to support poorly performing systems that keep breaking down as more demand and integration is placed onto them. Continuing to operate with these legacy systems will undermine ORAs ability to perform its mission.

3. **Provide a list of this investment's accomplishments in the prior year (PY), including projects or useful components/project segments completed, new functionality added, or operational efficiency achieved.**

MARCS has produced a number of useful components or project segments in the prior year. This includes Data Sharing Services (DSS) to support sharing data between ORA and the

Centers. Notification Services (NS) to provide notifications by email and fax. Standardized Evidence and Reference Services (SERS) updates to provide access to electronic documents. Work Assignment and Accomplishment Manager (WAAM) for Recall Audit Checks (RAC) to support RAC functionality. This crosses other MARCS components as delineated below and is new functionality for FDA. Field Work Manager (FWM) for RAC Recall Enterprise System (RES) updates for RAC Electronic State Access to FACTS (eSAF) updates for RAC In addition, MARCS has also accomplished: Implementation of concurrent review for compliance activities in the Compliance Management System (CMS). Implementation of FSMA Section 304 for Prior Notice in PNSI and OASIS. Rollout of PREDICT to an additional 6 districts in ORA.

4. **Provide a list of planned accomplishments for current year (CY) and budget year (BY).**

MARCS plans to accomplish in CY (FSMA requirements (question 3.a) are implicit throughout this section): Complete the national rollout of PREDICT functionality. Release of RAC functionality. Release of updated PREDICT and ITACS functionality. Further development of ARRMS to support authorizations, roles, and responsibilities to provide a robust and flexible security scheme. This is dependent on the acquisition of Oracle technologies and the provisioning of environments with needed hardware. Redesign and enhancement of FMS to provide better and more robust firm and firm information management, which is needed in virtually all of the ORA work flows. This is dependent on an appropriate technology choice for indexing large databases. Development of DGS to provide the ability to manage, build, and revise templates and generate documents with pre-populated information. Development of PS to support using and building product codes. Development of DLCMS to support the management of reference data including giving FTEs the ability to edit data without having to go through a maintenance release. Development of UWES to provide a standardized and robust user interface across all of MARCS. Development of Inspection, Investigation, Field Exam, and Sample Collection functionality in FWM. Development of support for Inspection, Investigation, Field Exam, and Sample Collection functionality in WAAM. Development of RAD functionality. Migration of 801(a) imports from OASIS into EM, with enhancements. Requirements for the development of PNM to handle 801(m) imports. Development of a RAD pilot to support aspects of Inspections. MARCS plans to accomplish in BY: Release for ARRMS, FMS, DGS, PS, DLCMS, and UWES. Release for Inspection and Investigation functionality for FWM and WAAM. Release for domestic Field Exam and Sample Collection functionality for FWM and WAAM. Development of support for Sample Analysis, including integration with ALM. Support for the rollout of releases across ORA. Development for account management to ITACS.

5. **Provide the date of the Charter establishing the required Integrated Program Team (IPT) for this investment. An IPT must always include, but is not limited to: a qualified fully-dedicated IT program manager, a contract specialist, an information technology specialist, a security specialist and a business process owner before OMB will approve this program investment budget. IT Program Manager, Business Process Owner and Contract Specialist must be Government Employees.**

2010-01-29

Section C: Summary of Funding (Budget Authority for Capital Assets)

1.

Table I.C.1 Summary of Funding

	PY-1 & Prior	PY 2011	CY 2012	BY 2013
Planning Costs:	$6.9	$0.7	$0.5	$0.2
DME (Excluding Planning) Costs:	$73.5	$29.7	$18.9	$10.7
DME (Including Planning) Govt. FTEs:	$5.1	$0.8	$0.8	$0.8
Sub-Total DME (Including Govt. FTE):	$85.5	$31.2	$20.2	$11.7
O & M Costs:	$32.3	$5.8	$9.2	$6.4
O & M Govt. FTEs:	$1.8	$0.3	$0.3	$0.4
Sub-Total O & M Costs (Including Govt. FTE):	$34.1	$6.1	$9.5	$6.8
Total Cost (Including Govt. FTE):	$119.6	$37.3	$29.7	$18.5
Total Govt. FTE costs:	$6.9	$1.1	$1.1	$1.2
# of FTE rep by costs:	8	8	8	9
Total change from prior year final President's Budget ($)		$6.4	$0.6	
Total change from prior year final President's Budget (%)		20.96%	1.90%	

2. If the funding levels have changed from the FY 2012 President's Budget request for PY or CY, briefly explain those changes:

Funding levels have been increased in order to address the new requirements from FSMA. MARCS is expected to support functionality defined in the following areas of FSMA: Sec. 103 Sec. 104 Sec. 105 Sec. 106 Sec. 107 Sec. 110 Sec. 111 Sec. 113 Sec. 114 Sec. 115 Sec. 201 Sec. 202 Sec. 204 Sec. 205 Sec. 206 Sec. 207 Sec. 210 Sec. 301 Sec. 302 Sec. 303 Sec. 304 Sec. 306 Sec. 307 Sec. 308 Sec. 309

Section D: Acquisition/Contract Strategy (All Capital Assets)

Table I.D.1 Contracts and Acquisition Strategy

Contract Type	EVM Required	Contracting Agency ID	Procurement Instrument Identifier (PIID)	Indefinite Delivery Vehicle (IDV) Reference ID	IDV Agency ID	Solicitation ID	Ultimate Contract Value ($M)	Type	PBSA ?	Effective Date	Actual or Expected End Date
Awarded	7524	INN10PC18073									
Awarded	7524	HHSF223201000047I									
Awarded	7524	HHSF223201010727G									
Awarded	7529	HHSN276200900249U	W91QUZ06A0003	9700							
Awarded	7529	HHSN276200900249U	W91QUZ06A0003	9700							
Awarded	7524	HHSF223200850026C									
Awarded	7524	IND11PX19157									

2. If earned value is not required or will not be a contract requirement for any of the contracts or task orders above, explain why:
Item number 4 (HHSN276200900249U) is for the purchase of software only. There are no services involved. As this is a purchase only, EVM is not required since the schedule, cost, and earned value will be the same at the time the software licenses are acquired. Software license maintenance is also included beyond the base period. Item number 5 (in solicitation) is for the purchase of software only. There are no services involved. As this is a purchase only, EVM is not required since the schedule, cost, and earned value will be the same at the time the software licenses are acquired. Software license maintenance is also included beyond the base period.

Exhibit 300B: Performance Measurement Report

Section A: General Information

Date of Last Change to Activities: 2012-02-23

Section B: Project Execution Data

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
286120	FDA ORA MARCS Program Management and Technical Integration (PMTI)	This project provides program level activities to support work across all of MARCS, in particular for non functional testing and implementation. MARCS is divided into a set of components. There are application and service components. The work flows in ORA will often cross multiple organizations and include a number of different user activity types such as screening, field exams, sample collections, sample analysis, and compliance. The application components are designed to provide user groups with a one stop shop interface that will allow them to perform work from their user point of view. Functionality is only implemented once in a component. One user group work flow may use functionality from most of the MARCS components. This has implications for the management of MARCS. While the individual projects build out certain types of			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		functionality, these need to be combined and coordinated into a whole in order to provide a useful work flow that covers the whole life cycle of a regulated product as it passes from one user group to the next. This combination and coordination needs to occur at the program level rather than in individual projects. Providing this glue to produce a holistic and comprehensive system is the goal of PMTI. Because of this approach, most of the EPLC stage gates are handled at the release level rather than at the project level. Each MARCS release is composed of functionality produced by one or more projects that has been logically grouped to support work flows. PMTI includes work for MARCS 0.5, 1.0, 1.1, and 2.0 releases. Work for a release will begin 6 - 12 months before that release is scheduled. PMTI begins work on a release when it is time to start system integration testing. Work for a release includes system integration testing, promotion to the pre-production environment, performance testing, user acceptance testing, promotion to the production environment, security testing, and then release. Program management in this project includes release management and management of dependencies. This also includes system architecture, a road map, inter project coordination, decision analysis			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		(for technology and platform selection), security work, user experience management (user friendly and consistent interface), inter project requirements management, status meetings, reports, risk management, and configuration management. This project is the point at which the prime contractor is responsible for MARCS.			
286177	FDA ORA MARCS Food Safety Modernization Act (FSMA)	This project implemented functionality for Section 304 of FSMA. This is Prior Notice functionality required for 801(m) screening that had a legislative deadline for implementation and involved changes to Operational and Administrative System for Imports Support (OASIS) and Prior Notice System Interface (PNSI).			
286202	FDA ORA MARCS Authorization, Roles, and Responsibilities Management Services (ARRMS) 2	ARRMS provides all of the security for MARCS. This is designed to be a dynamic security approach that gives Field supervisors flexibility and fine grained control in assigning privileges, whether permanently or on a temporary basis. This project is a continuation of ARRMS to implement roles and organizations capability using the Oracle Identity Management suite of COTS products and focuses on roles and organizations. ARRMS focused on gathering requirements and this project is building a portion of those requirements. Due to the geographically dispersed nature of the ORA organization and that regulated products will often			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		travel from one district to another, ORA has some particular security requirements to deal with this that are not offered in any COTS that has been identified. Custom software will be built to provide this specialized functionality.			
286210	FDA ORA MARCS Field Work Manager (FWM) 2	FWM 2 builds on and continues the work from FWM. The FWM component will provide all of the functionality for completing Field work. This is work where an FDA person does actual work dealing directly with a regulated product. FWM 2 includes work on recall audit checks, inspections, investigations, field exams, and sample collections. FWM 2 is focused on completing recall audit check, building inspections and import field exams, and gathering requirements for domestic field exams, sample collections, sample analysis, and other activities. Field operations is one of the six domains that make up the ORA work flows. FWM is the component that will provide the functionality for this domain. This is a large set of functionality that is being built out over a set of projects. Functionality is built out in an incremental fashion where, for example, one project might focus on requirements and design and another project would focus on development and test. This is the case for recall audit check, which was partly built in FWM but will now be finished in FWM 2. Functionality in this component is			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		being built for two separate user platforms. It will be available on the standard FDA laptops. It will also be available on Remote Access Devices (RADs). RADs are handheld devices. This includes an investigation into potential RAD platforms and a recommendation for this. This is the first time a RAD will be directly integrated with the FDA network, so a number of issues need to be resolved. In addition, functionality on laptops and RADs will be available in two modes: online and offline. An offline mode is needed as Field work is often done in remote locations with little or no connectivity. The technology that is being used to implement this is Sybase SQL Anywhere and Afaria. FWM 2 includes work to incorporate this technology and build up the FDA infrastructure to support this.			
286212	FDA ORA MARCS Entry Manager (EM)	This project will migrate current functionality that exists in Operational and Administrative System for Import Support (OASIS) for Entry Query to EM. This will also include enhancements of this functionality. In addition, this will also include gathering requirements for the field exam and sample collection functionality that exists in OASIS that will be migrated to FWM and WAAM.			
286215	FDA ORA MARCS Predictive Risk-based Evaluation and Dynamic Import Compliance	This project is focused on improving current Extract, Transform, and Load (ETL)			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
	Targeting (PREDICT)	methods, on integrating PREDICT with the use of Dunn and Bradstreet (DnB) data for verifying firm information, and starting on Rules Studio.			
286216	FDA ORA MARCS Document Generator Services (DGS)	This project is building a service to support the creation and management of templates across all of ORA. Because of the geographically dispersed nature of ORA, different regional locations have different processes and also often have different templates and forms. Much of this has never been included in the past as part of an electronic system. DGS will provide a means for this documentation to be standardized across all of ORA via MARCS. This dovetails with the Automated Laboratory Management (ALM) Quality Management Information System (QMiS). DGS will integrate wtih QMiS to support improving quality across ORA as an organization.			
286217	FDA ORA MARCS Work Assignment and Accomplishment Manager (WAAM) 2	WAAM 2 builds on and continues the work from WAAM. WAAM will provide all of the work management functionality for MARCS. This includes the ability to assign and track work, record time, and to automatically route work. The work in this project will support development that is occurring in FWM 2 and EM. WAAM 2 will provide functionality to support the work flows that are being built in these two projects. WAAM 2 also includes requirements gathering to dovetail with the requirements			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		gathering in FWM 2 and EM 2. The functionality provided by WAAM will be used by all of the ORA work flows in MARCS. This also includes Work Planner, which will be used to produce the national work plan for ORA.			
286227	FDA ORA MARCS Program Management and Technical Integration (PMTI) 2	This project will provide program level activities to support work across all of MARCS. The combination and coordination of work needs to occur at the MARCS program level rather than in individual projects. Providing this glue to produce a holistic and comprehensive system is the goal of PMTI 2. Because of this approach, most of the EPLC stage gates are handled at the release level rather than at the project level. Each MARCS release is composed of functionality produced by one or more projects that has been logically grouped to support work flows. This includes work for MARCS 0.5, 1.0, 1.1, 2.0, 2.1, and 2.2 releases. Work for a release will begin 6 - 12 months before that release is scheduled. PMTI 2 will begin work on a release when it is time to being system integration testing. Work for a release includes system integration testing, promotion to the pre-production environment, performance testing, user acceptance testing, promotion to the production environment, security testing, and then release. Project and program management in this project			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		includes release management and management of individual projects. This also includes system architecture, a road map, inter project coordination, decision analysis (for technology and platform selection), security work, user experience management (MARCS user friendly and consistent interface), inter project requirements management, status meetings, reports, risk management, and configuration management. This project is the point at which the prime contractor is responsible for MARCS. MARCS 0.5 includes Data Sharing Services (DSS) and Center Views (CV). MARCS 1.0 includes functionality for Recall Audit Checks by FDA and State personnel. MARCS 1.1 includes enhancements to Predictive Risk-based Evaluation and Dynamic Import Compliance Targeting (PREDICT) to support import screening. MARCS 2.0 includes ARRMS, Import Trade Auxiliary Communications System (ITACS), and enhancements to some of the MARCS services. MARCS 2.1 includes DGS, Product Services (PS), Date Lookup and Code Management Services (DLCMS), User Workspace Enhancement Services (UWES), and Firm Management Services (FMS). MARCS 2.2 includes functionality for inspections and investigations.			
286235	FDA ORA MARCS Data	This project will provide program			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
	Integration (DI)	wide data integration. The MARCS data structure is being re-factored and redesigned to provide a unified data set. As each project progresses in its work, this project is charged with ensuring that a unified MARCS data set that will be contained within one MARCS database is produced. As MARCS is being built out as a set of components within individual projects, a program level view is needed to address the production of a consistent and unified data set that will cover all of the work flows for MARCS. This directly supports the ability of MARCS to integrate the ORA work flows and also integrate with other areas of FDA and external partners. This data integration impacts and supports all of the MARCS projects.			
286255	FDA ORA MARCS Authorization, Roles, and Responsibilities Management Services (ARRMS) 2-Supplemental	ARRMS provides all of the security for MARCS. This is designed to be a dynamic security approach that gives Field supervisors flexibility and fine grained control in assigning privileges, whether permanently or on a temporary basis. This project is a continuation of ARRMS 2 to implement roles and organizations capability using the Oracle Identity Management (IDM) suite of COTS products and focuses on roles and organizations. Due to the geographically dispersed nature of the ORA organization and that regulated products will often travel from one district to another,			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		ORA has some particular security requirements to deal with this that are not offered in any COTS that has been identified. Custom software will be built to provide this specialized functionality.			
286276	FDA ORA MARCS Firm Management Services (FMS)	FMS will provide a single, fully encapsulating service for accessing firm information in MARCS. Firm information is used in virtually every work flow in MARCS. This will take multiple legacy implementations of this functionality, enhance, and improve them, and provide a standardized interface for all of MARCS. FMS will provide functionality to add, edit, merge, unmerge, and delete Firm Establishment Identifiers (FEIs). Each physical location of a regulated organization is a separate FEI. In addition, different types of products that are in one physical location will often require different FEIs. It is not uncommon for a large conglomerate to have multiple FEIs. Managing this information is a perpetual challenge as this information is always changing as firms continually change. In addition, information received, especially from foreign firms, is often not correct or complete and needs to be massaged to identify FEIs. FMS interfaces directly with the Regulatory Business Information Services (RBIS) Firm Master List Services (FMLS) to support FEI data quality. Producing FMS as a fully encapsulating service will give			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		MARCS users a one stop shop for dealing with firm information.			
286277	FDA ORA MARCS Field Work Manager (FWM) 3	FWM 3 builds on and continues the work from FWM 2. The FWM component will provide all of the functionality for completing Field work. This is work where an FDA person does actual work dealing directly with a regulated product. FWM 3 includes work on inspections, investigations, field exams, sample collections, portions of sample analysis, third party certification and auditing (TPCA), and compliance follow up. FWM 3 will focus on completing inspections, building investigations, field exams, and sample collections, gathering requirements for sample analysis, TPCA, and compliance follow up. Field operations is one of the six domains that make up the ORA work flows. FWM is the component that will provide the functionality for this domain. This is a large set of functionality that is being built out over a set of projects. Functionality is built out in an incremental fashion where, for example, one project might focus on requirements and design and another project would focus on development and test. This is the case for inspections, which was mostly built in FWM 2 but will now be finished in FWM 3. Functionality in this component is being built for two separate user platforms. It will be available on the standard FDA laptops. It will also be available on Remote Access Devices (RADs). RADs			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		are handheld devices. A pilot will be conducted using Apple and Android products to prove out the expected ROI and determine a final RAD platform. This is the first time a RAD will be directly integrated with the FDA network, so a number of issues need to be resolved. In addition, functionality on laptops and RADs will be available in two modes: online and offline. An offline mode is needed as Field work is often done in remote locations with little or no connectivity. The technology that is being used to implement this is Sybase SQL Anywhere and Afaria. FWM 3 includes work to incorporate this technology and build up the FDA infrastructure to support this.			
286294	FDA ORA MARCS Imports 2	Imports 2 will contain work for Entry Manager (EM), Import Trade Auxiliary Communications System (ITACS), Predictive Rick-based Evaluation and Dynamic Import Compliance Targeting (PREDICT), Prior Notice Manager (PNM), and Customs System Interface (CSI). For EM, this will focus on migrating functionality from the legacy systems Operational and Administrate System for Import Support (OASIS) and Entry Review to support 801(a) screening. For ITACS, this will focus on account management (via Authorization, Roles, and Responsibilities Management Services (ARRMS)) and additional functionality enabled by			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		logins. For PREDICT, this will focus on building functionality to better manage rules. For PNM and CSI, this will focus on requirements. EM will provide functionality for screening, in conjunction with PREDICT, for the majority of the 20,000,000+ products imported via the 801(a) process annually. This will give import screeners and import compliance officers a unified interface for dealing with all of their work flows, including tracking Field Work (accomplished in Field Work Manager (FWM)). PREDICT is an expert system built around a rules engine that produces a risk-based score of imported products. Products with a low score are automatically sent forward by PREDICT. Products with a higher score require an import screener to review the product by using EM. ITACS is used to interface with import filers and industry to provide a conduit for supporting documentation. This will reduce the current use of phone calls and emails, provide FDA with a more reliable information source and record, and give industry a more efficient way of communicating. Use of this component by industry is voluntary, so it must provide an incentive for external partners. PNM will provide the interface for work flows associated with 801(m) import screening, Prior Notice, which is focused on Food Security and Food Safety. This			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		will replace functionality currently in OASIS. CSI will replace the outdated technology currently used for the interface between FDA and Customs and Border Protection (CBP). Work on CSI is dependent upon and must be done in conjunction with CBP so as to accommodate CBP modifications and enhancements.			
286295	FDA ORA MARCS Support Services (SS)	MARCS contains a number of aggregate services that are being built to provide functionality across all of MARCS and potentially outside of MARCS. Support Services (SS) includes work for Data Sharing Services (DSS), Standardized Evidence and Reference Services (SERS), Notification Services (NS), Data Look up and Code Management Services (DLCMS), Product Services (PS), and User Workspace Enhancement Services (UWES). Work for DSS, SERS, and NS focuses on final changes to fully conform to the new MARCS architecture. DSS currently provides for materialized views of Center databases in order to give MARCS users 24x7 access to this Center data. This may be expanded in the future for data sharing needs within FDA and with external partners. SERS provides a programmatic and user interface for the storage and retrieval of documents (including photographs, scanned items, and other evidence) to support the regulatory and legal requirements of ORA. NS provides automated			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		communication via email and fax for use within FDA and with external partners. DLCMS, PS, and UWES will be built under SS. DLCMS will provide functionality for non technical government FTEs to manage reference data used to identify products and activities. Currently, this can only be changed by engaging technical personnel to adjust information in tables. PS will combine the best of breed of six separate legacy implementations for managing, searching, and updating regulatory product information. This information originates in the Centers, but is used by ORA in many of its work flows, so ORA needs a service to support the management and aggregation of this product information. UWES will use the COTS Oracle WebCenter product to provide a unified and consistent portal-like user experience across all of MARCS. The user view will be customized according to role. In addition, individual users will be able to customize their view of application components to present information in the manner that is most useful to that user.			
286296	FDA ORA MARCS Work Assignment and Accomplishment Manager (WAAM) 3	WAAM 3 builds on and continues the work from WAAM 2. WAAM will provide all of the work management functionality for MARCS. This includes the ability to plan work, assign and track work, record time, and to			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		automatically route work. The work in this project will support development that is occurring in FWM 3 and Imports 2. WAAM 3 will provide functionality to support the work flows that are being built in these two projects. WAAM 3 also includes requirements gathering to dovetail with the requirements gathering in FWM 3 and Imports 2. The functionality provided by WAAM will be used by all of the ORA work flows in MARCS. WAAM will provide functionality that will be used by all of the application components in MARCS. WAAM will be used to implement the annual ORA work plan. This is a plan that maps out the inspection, field exam, sample collection, and other field work activities for a fiscal year for ORA. This plan is produced in conjunction with the Centers and focuses on targeting areas that are deemed to be high risk. WAAM will also be used to track work that occurs outside of the annual ORA work plan. ORA field work has to respond to emerging threats and actual incidents as they occur. WAAM provides the flexibility for ORA to work towards the annual ORA work plan while also dealing with things as they happen. WAAM will be used to track discrete work units to provide a full accounting of what has been done and by whom and to support connecting a set of work activities with a particular regulatory or compliance action,			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		including providing evidence for legal proceedings.			
286298	FDA ORA MARCS Software Acquisition for Oracle Technologies	This is a software acquisition of COTS technologies. This includes an expansion of the licenses for the BPMS (Business Process Management Suite) (including Enterprise Service Bus (ESB) and Service Oriented Architecture (SOA)), Oracle Identity Management (IDM) Suite, WebCenter, Oracle Policy Automation (OPA), and Real User Experience Insight (RUEI). The license expansion for the BPMS includes enough licenses for all FDA users. A number of FDA Centers have expressed interest in using this platform for their systems. MARCS has a primary focus on integration across the organization and as the BPMS would help further this goal, these licenses have been expanded to enable organization wide integration. IDM will give MARCS a comprehensive COTS solution to provide the specialized functionality and fine grained security control envisioned. This will require some custom code to realize envisioned functionality. The custom code will be developed under Authorization, Roles, and Responsibilities Management Services (ARRMS) 2 – Supplemental. IDM may also be leveraged as an FDA wide solution in the future. The implementation of IDM will be used by every component within MARCS. This has been vetted with the FDA CIO and HHS CIO			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		and conforms to HHS standard security. WebCenter provides robust user interface and portal capabilities. This COTS will be used to implement User Workspace Enhancement Services (UWES), which is part of the Support Services project. UWES will provide a standardized user experience customized based on user role and single user preferences. OPA is a rules engine that will have a number of applications in MARCS ranging from inspection preparation, intelligent questionnaires, and import screening support. RUEI is a tool that can be used from a centralized location to determine the experience that an end user at a remote site is having. ORA is a geographically dispersed organization. In this sense, the user community for MARCS is different from Center user communities since the vast majority of users are not in the Washington, DC metropolitan area. This tool will give ORA and OIM a new ability to understand what is actually happening at user sites and will enable a systematic approach towards improving performance and reliability in the Field. The software acquired will be used in all of the MARCS projects going forward to one degree or another and will enable MARCS functionality that will be realized in releases.			
306567	FDA ORA MARCS Authorization,	ARRMS provides all of the			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
	Roles, and Responsibilities Management Services (ARRMS) 3	security for MARCS. This is designed to be a dynamic security approach that gives Field supervisors flexibility and fine grained control in assigning privileges, whether permanently or on a temporary basis. This project is a continuation of ARRMS 2 Supplemental to implement roles and organizations capability using the Oracle Identity Management (IDM) suite of COTS products. Due to the geographically dispersed nature of the ORA organization and that regulated products will often travel from one district to another, ORA has some particular security requirements to deal with this that are not offered in any COTS that has been identified. Custom software will be built to provide this specialized functionality. In addition, ARRMS 3 will expand upon ARRMS functionality to include synchronization with legacy systems, providing a replacement for the MARCS Identity Management (MIM) component, incorporate additional MARCS components into the security services provided by ARRMS, auditing and reporting capabilities, maintain and purge authorizations, integrate with Regulatory Business Information Services (RBIS) and Automated Laboratory Management (ALM) Laboratory Information Management System (LIMS), and upgrade to 11gR2.			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
306574	FDA ORA MARCS Field Work Manager (FWM) 4	FWM 4 is focused on refactoring product from FWM 2 that was used to realize Recall Audit Check (RAC) functionality. FDA made an organizational level decision to use the Oracle Exadata and Exalogic platform. The code for RAC needs to be refactored and upgraded in order to support the use of this new hardware platform. Not doing this introduces unnecessary technical risk for MARCS. The FWM component will provide all of the functionality for completing Field work. This is work where an FDA person does actual work dealing directly with a regulated product. Field operations is one of the six domains that make up the ORA work flows. FWM is the component that will provide the functionality for this domain. This is a large set of functionality that is being built out over a set of projects, often in conjunction with work on WAAM. Functionality is built out in an incremental fashion where, for example, one project might focus on requirements and design and another project would focus on development and test.			
306581	FDA ORA MARCS Work Assignment and Accomplishment Manager (WAAM) 4	WAAM 4 is focused on refactoring product from WAAM 2 that was used to realize Recall Audit Check (RAC) functionality. FDA made an organizational level decision to use the Oracle Exadata and Exalogic platform. The code for RAC needs to be refactored and upgraded in order to support the use of this new hardware platform. Not doing this			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		introduces unnecessary technical risk for MARCS. In addition, WAAM 4 will complete the build out of functionality needed for the National Sample Distributor (NSD), which is part of Work Manager. NSD is used to route samples collected by the ORA Field to an appropriate and available laboratory. This will be an important integration point between MARCS and the Automated Laboratory Management (ALM) Laboratory Information Management System (LIMS). The WAAM component will be used to plan, assign, and track all work in MARCS. The functionality provided by WAAM will be used by all of the ORA work flows in MARCS. WAAM will provide functionality that will be used by all of the application components in MARCS. WAAM functionality is being built out over a set of projects, often in conjunction with work on FWM. Functionality is built out in an incremental fashion where, for example, one project might focus on requirements and design and another project would focus on development and test.			

Activity Summary

Roll-up of Information Provided in Lowest Level Child Activities

Project ID	Name	Total Cost of Project Activities ($M)	End Point Schedule Variance (in days)	End Point Schedule Variance (%)	Cost Variance ($M)	Cost Variance (%)	Total Planned Cost ($M)	Count of Activities
286120	FDA ORA MARCS							

Activity Summary

Roll-up of Information Provided in Lowest Level Child Activities

Project ID	Name	Total Cost of Project Activities ($M)	End Point Schedule Variance (in days)	End Point Schedule Variance (%)	Cost Variance ($M)	Cost Variance (%)	Total Planned Cost ($M)	Count of Activities
	Program Management and Technical Integration (PMTI)							
286177	FDA ORA MARCS Food Safety Modernization Act (FSMA)							
286202	FDA ORA MARCS Authorization, Roles, and Responsibilities Management Services (ARRMS) 2							
286210	FDA ORA MARCS Field Work Manager (FWM) 2							
286212	FDA ORA MARCS Entry Manager (EM)							
286215	FDA ORA MARCS Predictive Risk-based Evaluation and Dynamic Import Compliance Targeting (PREDICT)							
286216	FDA ORA MARCS Document Generator Services (DGS)							
286217	FDA ORA MARCS Work Assignment and Accomplishment Manager (WAAM) 2							
286227	FDA ORA MARCS Program Management and Technical Integration (PMTI) 2							
286235	FDA ORA MARCS Data Integration (DI)							

Activity Summary

Roll-up of Information Provided in Lowest Level Child Activities

Project ID	Name	Total Cost of Project Activities ($M)	End Point Schedule Variance (in days)	End Point Schedule Variance (%)	Cost Variance ($M)	Cost Variance (%)	Total Planned Cost ($M)	Count of Activities
286255	FDA ORA MARCS Authorization, Roles, and Responsibilities Management Services (ARRMS) 2-Supplemental							
286276	FDA ORA MARCS Firm Management Services (FMS)							
286277	FDA ORA MARCS Field Work Manager (FWM) 3							
286294	FDA ORA MARCS Imports 2							
286295	FDA ORA MARCS Support Services (SS)							
286296	FDA ORA MARCS Work Assignment and Accomplishment Manager (WAAM) 3							
286298	FDA ORA MARCS Software Acquisition for Oracle Technologies							
306567	FDA ORA MARCS Authorization, Roles, and Responsibilities Management Services (ARRMS) 3							
306574	FDA ORA MARCS Field Work Manager (FWM) 4							
306581	FDA ORA MARCS Work Assignment and Accomplishment Manager (WAAM) 4							

Activity Summary

Roll-up of Information Provided in Lowest Level Child Activities

Project ID	Name	Total Cost of Project Activities ($M)	End Point Schedule Variance (in days)	End Point Schedule Variance (%)	Cost Variance ($M)	Cost Variance (%)	Total Planned Cost ($M)	Count of Activities

Key Deliverables

Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
286120	286120: PMTI Program and Project Deliverables	This includes program and project management deliverables that are produced or significantly updated once during the execution of this project. This includes a Quality Assurance Plan (QAP), a Quality Assurance Surveillance Plan (QASP), Program Management Plan (PMP), Work Breakdown Structure (WBS) and dictionary, Risk Management Plan (RMP), Communications Plan (CP), Configuration Management Plan (CMP), Task Order Schedule (TOS), and Integrated Master Schedule (IMS).	2010-11-01	2010-11-01	2010-11-01	54	0	0.00%
286217	286217: WAAM 2 RAC Requirements Validation	RAC requirements were gathered in WAAM, but these requirements needed to be verified in relation to the use of the legacy Recall Enterprise System (RES) for supporting	2010-11-15	2010-11-15	2010-11-15	49	0	0.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		the work of ORA Field users.						
286202	286202: ARRMS 2 Requirements Validation and Decision Analysis	This conducted a survey and investigation into COTS products available and produced a recommendation for a COTS to fulfill most of the requirements for ARRMS.	2011-01-03	2011-01-03	2011-01-03	98	0	0.00%
286210	286210: FWM 2 Inspections Business Requirements	This built upon and refined requirements that had been gathered for Inspections in FWM. This includes inspection types not covered previously in FWM.	2011-01-12	2011-01-12	2011-01-12	96	0	0.00%
286212	286212: EM Business Requirements	This gathered requirements for Entry Query business considerations.	2011-01-17	2011-01-17	2011-01-17	112	0	0.00%
286210	286210: FWM 2 Import Field Exams Business Requirements	This gathered requirements for Import Field Exams.	2011-02-03	2011-02-03	2011-02-03	108	0	0.00%
286217	286217: WAAM 2 Import Field Exams Business Requirements	This is to gather business requirements for Import Field Exams. This focused on migrating and	2011-02-04	2011-02-04	2011-04-05	112	-60	-53.57%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		enhancing current functionality. It also included an examination of import and domestic field examination types to determine where terminology and method could be appropriately shared between the two.						
286216	286216: DGS Requirements for DGS	This gathered requirements for DGS functionality for MARCS.	2011-02-14	2011-02-14	2011-02-14	140	0	0.00%
286217	286217: WAAM 2 Domestic Field Exams, Sample Collection, National Sample Distributor, and Other Business Requirements	WAAM will need to support all of the regulatory work flows in ORA since it will be the hub of work within MARCS. This is to start collecting requirements for these future work types. This is for business related requirements that often deal with how to standardize procedures and approaches amongst different organizational units.	2011-02-17	2011-02-17	2011-02-17	132	0	0.00%
286210	286210: FWM 2 Offline Technologies Requirements	This is work specifically directed at offline functionalities	2011-02-17	2011-02-17	2011-02-17	143	0	0.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		and the expertise to produce functionality and support infrastructure using SQL Anywhere, Afaria, and Mobilink. This includes requirements for the envisioned functionality.						
286202	286202: ARRMS 2 Requirements Validation and Decision Analysis	This validated requirements to determine which ones would be fulfilled by a COTS and which ones would need custom development.	2011-02-28	2011-02-28	2011-02-28	124	0	0.00%
286120	286120: PMTI Program and Project Management Recurring Meetings and Deliverables, Including Stage Gates 1	This includes a number of activities that are recurring such as weekly meetings and status reports. Also included are IMS updates, risk list updates, Contract Performance Reports (CPR) for EVM, Stage Gates, internal meetings, other meetings with FDA, and other program and project management activities.	2011-03-07	2011-03-07	2011-03-07	180	0	0.00%
286216	286216: DGS Decision Analysis	An industry survey and analysis of COTS	2011-03-08	2011-03-08	2011-03-08	139	0	0.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		products was conducted. This resulted in a recommended product to implement the functionality envisioned for DGS.						
286217	286217: WAAM 2 Inspections Requirements	This produced requirements documentation. One of the goals is to increase the use of fielded data to eliminate redundant data entry and improve searching and reporting capabilities.	2011-03-09	2011-03-09	2011-03-09	147	0	0.00%
286210	286210: FWM 2 Sample Collection Requirements	This gathered requirements for supporting Sample Collection and Sample Analysis in FWM.	2011-03-15	2011-03-15	2011-03-15	146	0	0.00%
286210	286210: FWM 2 Inspections Design for User Interface and Logical	This produced a design to support Inspections both online and offline for laptops for user interfaces and logical software and data considerations.	2011-03-23	2011-03-23	2011-03-23	71	0	0.00%
286217	286217: WAAM 2 RAC Design for User Interface and Logical	This produced a design for WAAM that supports RAC functionality and also	2011-03-31	2011-03-31	2011-03-31	149	0	0.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		includes considerations for the future work management in relation to other types of Field activities for user interfaces and logical software and data considerations.						
286217	286217: WAAM 2 Import Field Exams Functional Requirements	This is to gather functional requirements for Import Field Exams	2011-04-15	2011-04-15	2011-07-12	67	-88	-131.34%
286210	286210: FWM 2 Offline Technologies Design	This is work specifically directed at offline functionalities and the expertise to produce functionality and support infrastructure using SQL Anywhere, Afaria, and Mobilink. This includes design for code, on device databases, server structure, and security considerations.	2011-04-22	2011-04-22	2011-04-22	171	0	0.00%
286216	286216: DGS Preliminary Design	This produced a preliminary design for DGS.	2011-04-28	2011-04-28	2011-04-28	87	0	0.00%
286217	286217: WAAM 2 RAC Design for Services Specifications	This produced a design for WAAM that supports RAC functionality and also includes considerations for the	2011-05-11	2011-05-11	2011-05-11	68	0	0.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		future work management in relation to other types of Field activities. This took into account functionality that will be needed from the various MARCS services.						
286210	286210: FWM 2 Inspections Functional, Non Functional, and User Interface Requirements	This built upon and refined requirements that had been gathered for Inspections in FWM. This included inspection types not covered previously in FWM.	2011-05-17	2011-05-17	2011-05-17	132	0	0.00%
286212	286212: EM Functional, Non Functional, and User Interface Requirements	This gathered requirements for Entry Query functionality, user interface, and non functional considerations.	2011-05-25	2011-05-25	2011-05-25	127	0	0.00%
286217	286217: WAAM 2 Work Planner Design for User Interface and Logical	This produced a design for WAAM that supports Work Planner for the annual plan for user interfaces and logical software and data considerations.	2011-05-26	2011-05-26	2011-05-26	93	0	0.00%
286217	286217: WAAM 2 RAC Design for Physical Data, Security, Interface,	This produced a design for WAAM that supports RAC functionality and also	2011-06-08	2011-06-08	2011-06-08	28	0	0.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
	and Data Synchronization	includes considerations for the future work management in relation to other types of Field activities. This took into account the physical data design, security ramifications, interface specifications, and considerations for migrating data.						
286210	286210: FWM 2 Import Field Exams Functional, Non Functional, and User Interface Requirements	This gathered requirements for Import Field Exams.	2011-06-17	2011-06-17	2011-06-21	133	-4	-3.01%
286217	286217: WAAM 2 Work Planner Business Requirements	One of the challenges faced by ORA is typing work performed correctly. There are a number of existing categories for work, but sometimes the definitions of these are not clear. There are also a number of situations that arise where someone performing Field work could classify that work in different ways using the current work taxonomy. This was addressed in this	2011-06-29	2011-06-29	2011-06-29	167	0	0.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		requirements gathering in order to make it more intuitive for Field users to classify their work according to what they actually do and give the ORA management structure the ability to plan work and pull reports.						
286202	286202: ARRMS 2 Requirements Validation Integration with ALM and RBIS	This validated requirements for integrating with ALM and RBIS in the future.	2011-07-08	2011-07-08	2011-07-08	144	0	0.00%
286212	286212: EM Preliminary Design	This produced a preliminary design for Entry Query functionality within EM.	2011-07-13	2011-07-13	2011-07-20	191	-7	-3.66%
286210	286210: FWM 2 Remote Access Device (RAD) Business Requirements	This gathered requirements for supporting RADs (handhelds) for conducting Field work. This resulted in a Decision Analysis Report that contained recommendations for platforms for RADs.	2011-07-14	2011-07-14	2011-07-14	163	0	0.00%
286210	286210: FWM 2 Inspections Design for Services Specifications	This produced a design to support Inspections both online and offline for	2011-07-14	2011-07-14	2011-07-14	169	0	0.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		laptops. This took into account functionality that will be needed from the various MARCS services.						
286202	286202: ARRMS 2 Design	This produced a design for incorporating the COTS chosen by FDA.	2011-07-31	2011-07-31	2011-07-31	191	0	0.00%
286210	286210: FWM 2 Sample Analysis Requirements	This gathered requirements for supporting Sample Collection and Sample Analysis in FWM.	2011-08-03	2011-08-03	2011-09-26	117	-54	-46.15%
286210	286210: FWM 2 Inspections Design for Physical Data, Security, Interfaces, and Data Synchronization	This produced a design to support Inspections both online and offline for laptops. This took into account the physical data design, security ramifications, interface specifications, and considerations for migrating data.	2011-08-03	2011-08-03	2011-08-03	99	0	0.00%
286216	286216: DGS Requirements for Integration with QMiS	This gathered requirements for integration with Automated Laboratory Management (ALM) Quality Management Information System	2011-08-05	2011-08-05	2011-08-05	60	0	0.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		(QMiS)						
286217	286217: WAAM 2 Work Planner Functional, Non Functional, and User Interface Requirements	This is to gather requirements for building Work Planner.	2011-08-11	2011-08-11	2011-08-11	41	0	0.00%
286210	286210: FWM 2 Remote Access Device (RAD) System Requirements	This gathered requirements for supporting RADs (handhelds) for conducting Field work. This resulted in a Decision Analysis Report that contained recommendations for platforms for RADs.	2011-08-12	2011-08-12	2011-08-12	28	0	0.00%
286217	286217: WAAM 2 Inspections Design for User Interface and Logical	This produced a design for WAAM that supports Inspections functionality and also includes considerations for the future work management in relation to other types of Field activities for user interfaces and logical software and data considerations.	2011-08-16	2011-08-16	2011-08-16	179	0	0.00%
286210	286210: FWM 2 Import Field Exams Design	This produced a design to support Import Field Exams both online and offline for laptops.	2011-08-17	2011-08-17	2011-09-26	110	-40	-36.36%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
286216	286216: DGS Final Design	This produced a final design for DGS.	2011-08-17	2011-08-17	2011-08-17	110	0	0.00%
286217	286217: WAAM 2 Work Planner Design for Services Specifications	This produced a design for WAAM that supports Work Planner for the annual plan. This took into account functionality that will be needed from the various MARCS services.	2011-08-25	2011-08-25	2011-08-25	91	0	0.00%
286212	286212: EM Field Exam and Sample Collection Requirements	This is for gathering requirements for the field exam and sample collection functionality that exists in OASIS that will be migrated to FWM and WAAM.	2011-08-31	2011-08-31	2011-08-31	183	0	0.00%
286217	286217: WAAM 2 Import Field Exams Non Functional and User Interface Requirements	This is to gather non functional and user interface requirements for Field Exams.	2011-08-31	2011-08-31	2011-09-26	55	-26	-47.27%
286217	286217: WAAM 2 Inspections Design for Services Specifications	This produced a design for WAAM that supports Inspections functionality and also includes considerations for the future work management in relation to other types of Field activities. This took into account functionality that will	2011-09-06	2011-09-06	2011-09-26	141	-20	-14.18%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		be needed from the various MARCS services.						
286120	286120: PMTI Program and Project Management Recurring Meetings and Deliverables, Including Stage Gates 2	This includes a number of activities that are recurring such as weekly meetings and status reports. Also included are IMS updates, risk list updates, Contract Performance Reports (CPR) for EVM, Stage Gates, internal meetings, other meetings with FDA, and other program and project management activities.	2011-09-07	2011-09-07	2011-09-07	183	0	0.00%
286217	286217: WAAM 2 Inspections Design for Physical Data, Security, Interfaces, and Data Synchronization	This produced a design for WAAM that supports Inspections functionality and also includes considerations for the future work management in relation to other types of Field activities. This took into account the physical data design, security ramifications, interface specifications, and considerations for migrating data.	2011-09-13	2011-09-13	2011-09-26	20	-13	-65.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
286217	286217: WAAM 2 Work Planner Design for Physical Data, Security, Interfaces, and Data Synchronization	This produced a design for WAAM that supports Work Planner for the annual plan. This took into account the physical data design, security ramifications, interface specifications, and considerations for migrating data.	2011-09-15	2011-09-15	2011-09-26	100	-11	-11.00%
286217	286217: WAAM 2 Domestic Field Exams, Sample Collection, National Sample Distributor, and Other Functional, Non Functional, and User Interface Requirements	WAAM will need to support all of the regulatory work flows in ORA since it will be the hub of work within MARCS. This is to start collecting requirements for these future work types. This is to gather requirements for realizing functionality.	2011-09-20	2011-09-20	2011-09-26	146	-6	-4.11%
286217	286217: WAAM 2 Work Planner Development	This produced code to realize Work Planner functionality.	2011-09-23	2011-09-23	2011-09-26	172	-3	-1.74%
286217	286217: WAAM 2 Work Planner Test	This is for conducting unit and regression testing for Work Planner functionality.	2011-09-26	2011-09-26	2011-09-26	69	0	0.00%
286217	286217: WAAM 2 Import Field Exams Design	This produced a design for WAAM that supports Import Field Exams functionality	2011-09-26	2011-09-26	2011-09-26	103	0	0.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		and also includes considerations for the Domestic Field Exams.						
286215	286215: PREDICT Rules Studio	This includes requirements, design, and some development for Rules Studio. Currently, when rules for PREDICT need to be modified, added, or removed, technical contract personnel need to make these modifications. This is to produce functionality that will allow non technical FTEs to make these modifications, additions, or deletions.	2011-09-28	2011-09-28	2011-09-28	153	0	0.00%
286298	286298: Software Acquisition for Oracle Technologies Parent Activity	This is a software acquisition of COTS technologies. This includes an expansion of the licenses for the BPMS (Business Process Management Suite) (including Enterprise Service Bus (ESB) and Service Oriented Architecture (SOA)), Oracle Identity Management (IDM)	2011-09-30	2011-09-30	2011-09-30	57	0	0.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		Suite, WebCenter, Oracle Policy Automation (OPA), and Real User Experience Insight (RUEI). The license expansion for the BPMS includes enough licenses for all FDA users. A number of FDA Centers have expressed interest in using this platform for their systems. MARCS has a primary focus on integration across the organization and as the BPMS would help further this goal, these licenses have been expanded to enable organization wide integration. IDM will give MARCS a comprehensive COTS solution to provide the specialized functionality and fine grained security control envisioned. This will require some custom code to realize envisioned functionality. The custom code will be developed under Authorization, Roles,						

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		and Responsibilities Management Services (ARRMS) 2 – Supplemental. IDM may also be leveraged as an FDA wide solution in the future. The implementation of IDM will be used by every component within MARCS. This has been vetted with the FDA CIO and HHS CIO and conforms to HHS standard security. WebCenter provides robust user interface and portal capabilities. This COTS will be used to implement User Workspace Enhancement Services (UWES), which is part of the Support Services project. UWES will provide a standardized user experience customized based on user role and single user preferences. OPA is a rules engine that will have a number of applications in						

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		MARCS ranging from inspection preparation, intelligent questionnaires, and import screening support. RUEI is a tool that can be used from a centralized location to determine the experience that an end user at a remote site is having. ORA is a geographically dispersed organization. In this sense, the user community for MARCS is different from Center user communities since the vast majority of users are not in the Washington, DC metropolitan area. This tool will give ORA and OIM a new ability to understand what is actually happening at user sites and will enable a systematic approach towards improving performance and reliability in the Field. The software acquired will be used in all of the MARCS projects going forward to one						

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		degree or another and will enable MARCS functionality that will be realized in releases.						
286255	286255: FDA ORA MARCS ARRMS 2 - Supplemental Startup Project Key Deliverables	Includes SRA Project Startup activities, the Project Initiation and Kickoff, development of the Project Management Plan Addendum, the project schedule, the Test Plan Addendum, and the Logical Data Model and Data Dictionary.	2011-10-25	2011-10-25	2011-10-25	60	0	0.00%
286212	286212: EM Final Design	This produced a final design for Entry Query functionality within EM.	2011-10-28	2011-10-28	2011-10-28	154	0	0.00%
286296	286296: WAAM 3 Project Startup Key Deliverables	Includes Contractor and FDA startup activities, Sprint planning, and key deliverables such as the project management plan addendum and schedule.	2011-11-10	2011-11-10	2011-11-14	44	-4	-9.09%
286295	286295: SS Startup Project Key Deliverables	Consists of the Contractor Project Startup activities, the Project Initiation and Kickoff, development of the QASP,	2011-11-18	2012-11-18	2011-12-23	86	-35	-40.70%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		development of the Project Management Plan Addendum, the project schedule, and the Software Development Plan.						
286277	286277: Group 1: FWM2 Completion and Startup Project Key Deliverables	This group is to complete Contractor Project Startup activities, the Project Initiation and Kickoff, development of the Project Management Plan Addendum, and the project schedule and for finalization of completion of work started under FWM2 including responding to comments for documents submitted under FWM2 for which we received comments under FWM3. Documents include the requirements documents for inspections, investigations, sample collections and field exams. In addition, the test report for FWM offline application for inspections.	2011-11-22	2011-11-22	2011-11-22	60	0	0.00%
286235	286235: DI Startup	Includes Contractor	2011-11-29	2011-11-29		82	-276	-336.59%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
	Project Key Deliverables	Project Startup activities, the Project Initiation and Kickoff, development of the Project Management Plan Addendum, and the project schedule.						
286235	286235: DI Quarterly Deliverables #1	Includes the first quarterly delivery of the Integrated Data Model, Integrated Data Dictionary, MARCS Common Vocabulary, Optimization Strategy Report, and Support Operations Report, as well as analysis of Predictive Risk-based Evaluation and Dynamic Import Compliance Targeting (PREDICT), Regulatory Business Information Services (RBIS), and Automated Laboratory Management (ALM) Laboratory Information Management System (LIMS) data approach and integration support.	2011-12-08	2011-12-08	2011-12-16	91	-8	-8.79%
286276	286276: Firm Management Services (FMS) – Business	The tasks in the Business Analysis package include a	2012-01-31	2012-01-31		130	-213	-163.85%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
	Analysis	Decision Analysis and Resolution (DAR) report, FMS Concept of Operations (CONOPS) report, and an analysis of existing firm services and data exchange procedures utilized by FMS, FMLS, FACTS/OASIS, and other FDA systems. The DAR will include an analysis of search tools that could be used to replace the current RetrievalWare product used by the Firm Finder application to search for firms. The CONOPS will provide an overview of the current, interim, and future state of FDA firm operations, including collaboration with the RBIS team to define a unified view of firm services provided by FMS and FMLS in the future state architecture. The requirements analysis of firm services and data exchange procedures will be used for						

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		planning purposes and constructing the user stories that will be assigned to each Agile sprint.						
286235	286235: DI Quarterly Deliverables #2	Includes the second quarterly delivery of the Integrated Data Model, Integrated Data Dictionary, MARCS Common Vocabulary, Optimization Strategy Report, and Support Operations Report, as well as continued analysis to develop the Predictive Risk-based Evaluation and Dynamic Import Compliance Targeting (PREDICT), Regulatory Business Information Services (RBIS), and Automated Laboratory Management (ALM) Laboratory Information Management System (LIMS) data approach and integration support.	2012-03-13	2012-03-13		95	-171	-180.00%
286227	286227: Program/Project Management, Period 1	Includes management of non-governmental activities of the MARCS program	2012-03-15	2012-03-15		189	-169	-89.42%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		including overall management and oversight of the program and task orders therein, management of release and change management control, quality assurance, communications, financial control, and earned value management for the first period of the task order.						
286227	286227: Integration Engineering, Period 1	Includes work completed by the technical architecture group which includes oversight of technical integration, integration engineering, maintenance of the MARCS roadmap, security engineering, enterprise architecture, management of the requirements, user experience, test, and development processes, and development of a LIMS strategy for rollout for the first period of the task order.	2012-03-15	2012-03-15		189	-169	-89.42%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
286296	286296: WAAM 3 Work Distributor Requirements and Design	Requirements and design for Work Distributor (WD) to replace National Sample Distributor (NSD). This work involves gathering requirements to complete laboratory administration and laboratory selection.	2012-03-22	2012-03-22		134	-162	-120.90%
286277	286277: Group 6: Gather Requirements for Barcode DAR and CONOPS for Employee Certifications and Audits	Consists of the requirements gathering and research activities for the production of a Decision Analysis Report (DAR) on hardware and software barcode solutions. It also consists of the activities for gathering requirements for the development of a concept of operations (CONOPS) for Employee Certifications and Audits. This includes conducting requirements gathering meetings with stakeholders to collect requirements then documenting the requirements, reviewing them and	2012-03-28	2012-03-28		187	-156	-83.42%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		preparing them for delivery. This will explore different technologies and solutions and produce recommendations.						
286296	286296: WAAM 3 Integration reqts for Laboratory Information Management System (LIMS), Laboratory Management Services (LM) , and Prior Notice Manager (PNM)	Development of requirements for Work Manager (WM) to integrate with Automated Laboratory Management (ALM) Laboratory Information Management System (LIMS), Laboratory Management Services (LM) and Prior Notice Manager (PNM). A Service Oriented Architecture (SOA) service specification will be delivered at the end of this work.	2012-04-23	2012-04-23		166	-130	-78.31%

Section C: Operational Data

Table II.C.1 Performance Metrics

Metric Description	Unit of Measure	FEA Performance Measurement Category Mapping	Measurement Condition	Baseline	Target for PY	Actual for PY	Target for CY	Reporting Frequency
Number of hours of unplanned down time due to applications the Prior Notice Center. The Bioterrorism Act of 2002 requires prior notice for imported food shipments. These need to be processed on a 24x7 basis. If the system is down, then these have to be processed manually. MARCS support for this activity on a 24x7 basis is key to food security. Aligns with 2012 Congressional Justification Performance Measure (CJ) 214201.	# of hours of unplanned down time per year	Customer Results - Service Quality	Under target	200.000000	180.000000	168.000000	160.000000	Semi-Annual
Percentage of field work flows designed for offline use. Activities that occur outside of a government facility (field activities) make up a significant portion of the work of	% of field work flows designed for offline use	Customer Results - Service Coverage	Over target	5.000000	10.000000	12.000000	15.000000	Semi-Annual

Table II.C.1 Performance Metrics								
Metric Description	Unit of Measure	FEA Performance Measurement Category Mapping	Measurement Condition	Baseline	Target for PY	Actual for PY	Target for CY	Reporting Frequency
ORA. Often these are in areas with no network connectivity. Providing the ability to conduct such work on a computer is key to improving the efficiency of field staff for imports, domestics, and foreign activities. Aligns with CJ 214205, 224201, 234202, 234203, 244202, 244203, 253201, and 254201.								
Number of imported products screened per year. FDA has to screen a product within two hours to meet CBP requirements to support the free flow of trade. The number of imported items has been steadily increasing and is projected to continue. PREDICT is used for risk based screening to support this throughput. Only a small portion of product can be inspected, so this screening is critical to	# of imported products screened per year	Process and Activities - Productivity	Over target	18000000.000000	19000000.000000	22684303.000000	20000000.000000	Monthly

Table II.C.1 Performance Metrics

Metric Description	Unit of Measure	FEA Performance Measurement Category Mapping	Measurement Condition	Baseline	Target for PY	Actual for PY	Target for CY	Reporting Frequency
protecting the public health. Supports CJ 214202 and 214204.								
Percentage of work flows handled via a Business Process Management System (BPMS) supported by an Enterprise Service Bus in a Service Oriented Architecture. This is the new MARCS architecture. Work flows in the past have crossed multiple legacy systems. This produces a disjointed approach. With the BPMS, these work flows will be united, increasing efficiency and the ability to share data within FDA. Aligns with CJ 214205, 224201, 234202, 234203, 244202, 244203, 253201, and 254201.	% of work flows	Technology - Effectiveness	Over target	0.000000	5.000000	5.000000	10.000000	Semi-Annual
Percentage of MARCS functionality re-engineered from legacy systems into new components. Legacy systems have outdated architectures and,	% of MARCS functionality re-engineered	Technology - Efficiency	Over target	5.000000	15.000000	15.000000	30.000000	Semi-Annual

Table II.C.1 Performance Metrics								
Metric Description	Unit of Measure	FEA Performance Measurement Category Mapping	Measurement Condition	Baseline	Target for PY	Actual for PY	Target for CY	Reporting Frequency
sometimes, are on obsolete technologies. Re-engineering these into the new MARCS architecture increases reliability and efficiency. Aligns with CJ 214205, 224201, 234202, 234203, 244202, 244203, 253201, and 254201.								